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Barker

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(54) **SIDE LOADING LEAD ANCHOR AND METHODS OF MAKING AND USING THEREOF**

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A61N 1/05 (2006.01)

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(58) **Field of Classification Search**
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See application file for complete search history.

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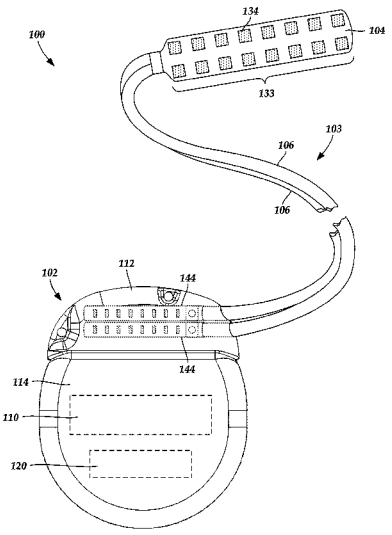
(57) **ABSTRACT**

An implantable lead anchor includes a first anchor housing, a second anchor housing, an armature, a spindle, and a locking arrangement. The first and second anchor housing each includes at least one channel to hold a portion of a lead. The armature is coupled to the first and the second anchor housings and holds the first and second anchor housings in a spaced-apart arrangement. A spindle is rotatably disposed on the armature and between the first and second anchor housing. In addition, the spindle includes a third channel to receive and hold a portion of a lead. The locking arrangement is formed on the spindle and at least one of the first or second anchor housing. The locking arrangement maintains the spindle in a rotated position relative to the first and second anchor housing when the locking arrangement is activated.

20 Claims, 7 Drawing Sheets



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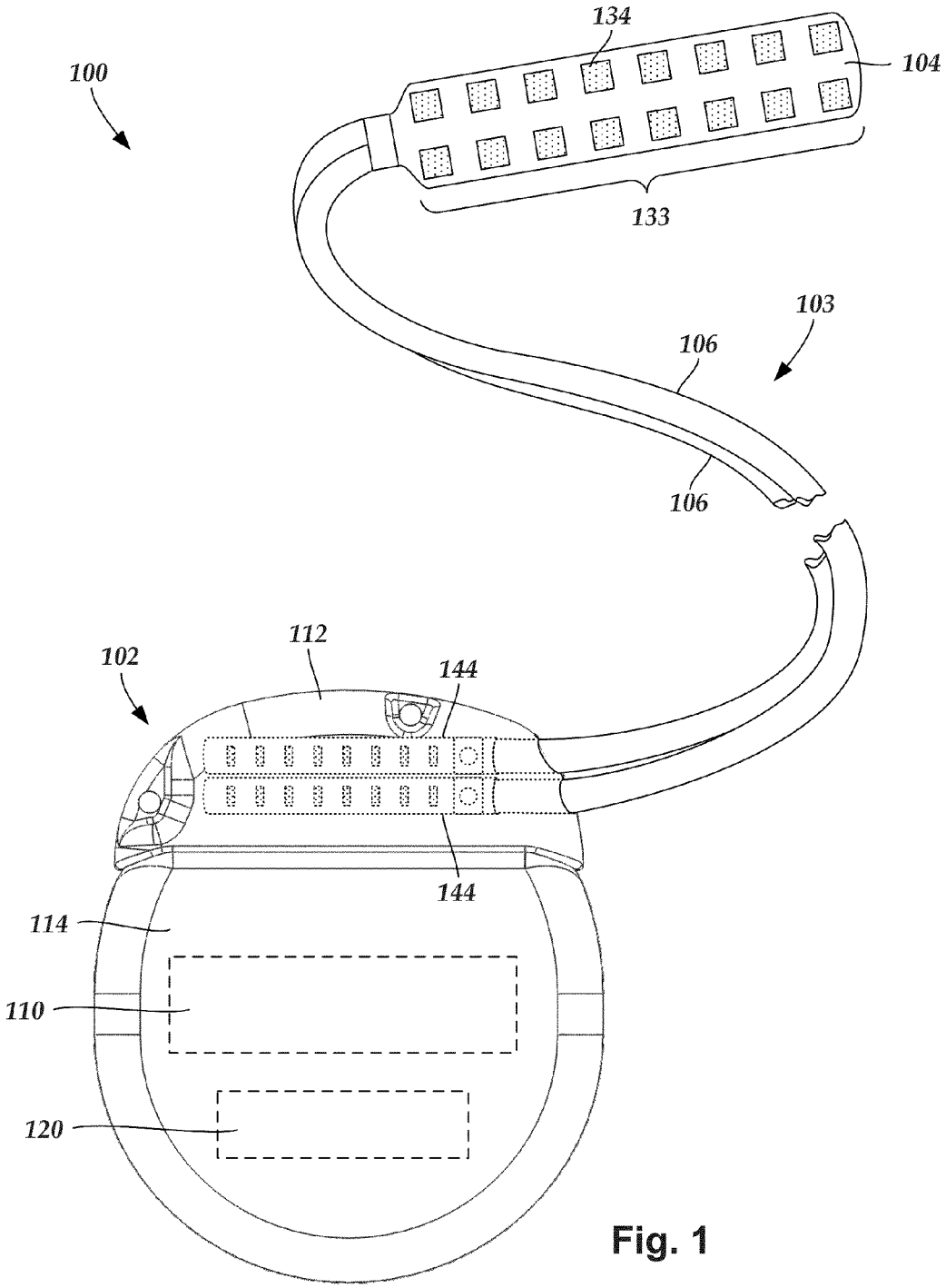

Fig. 1

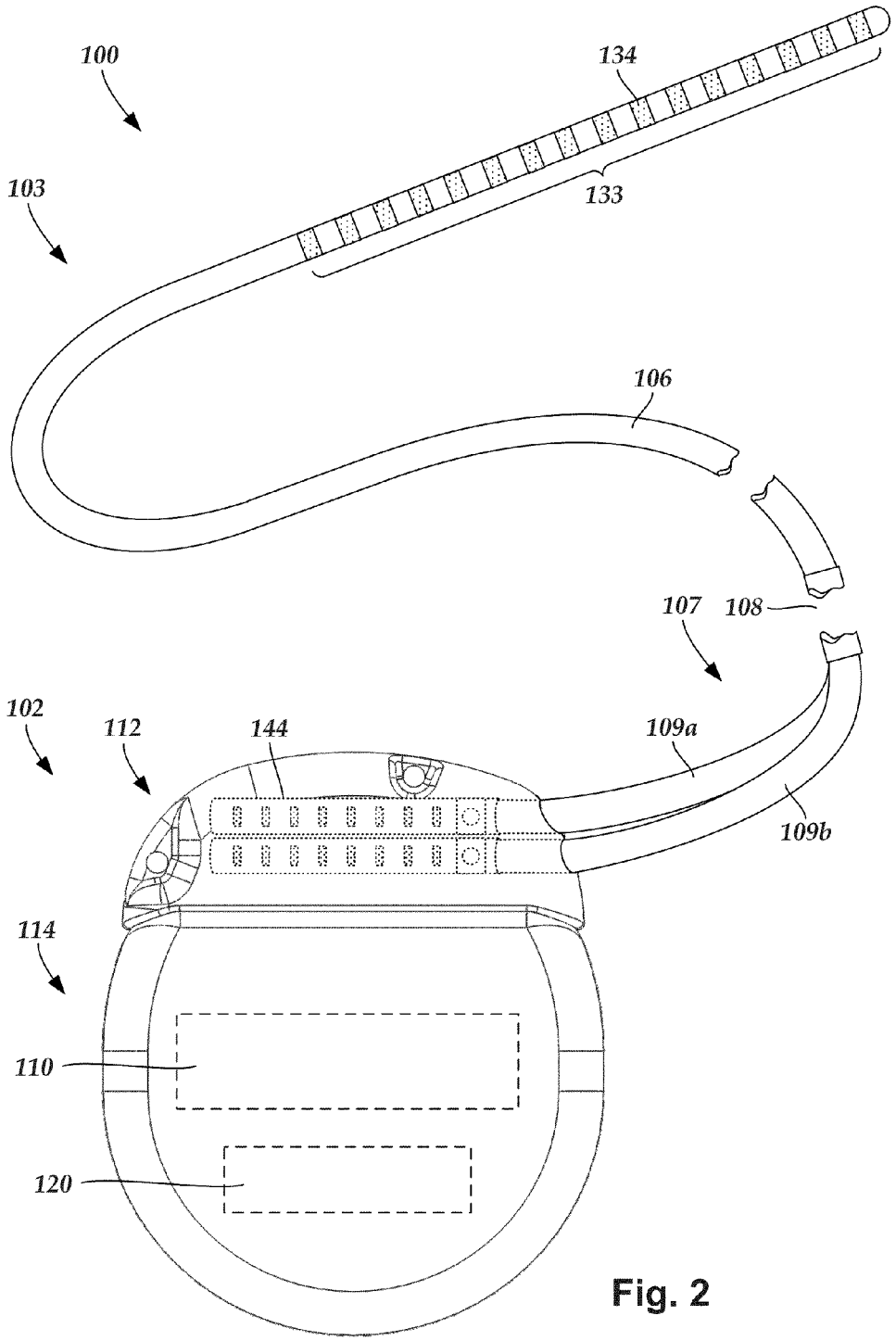

Fig. 2

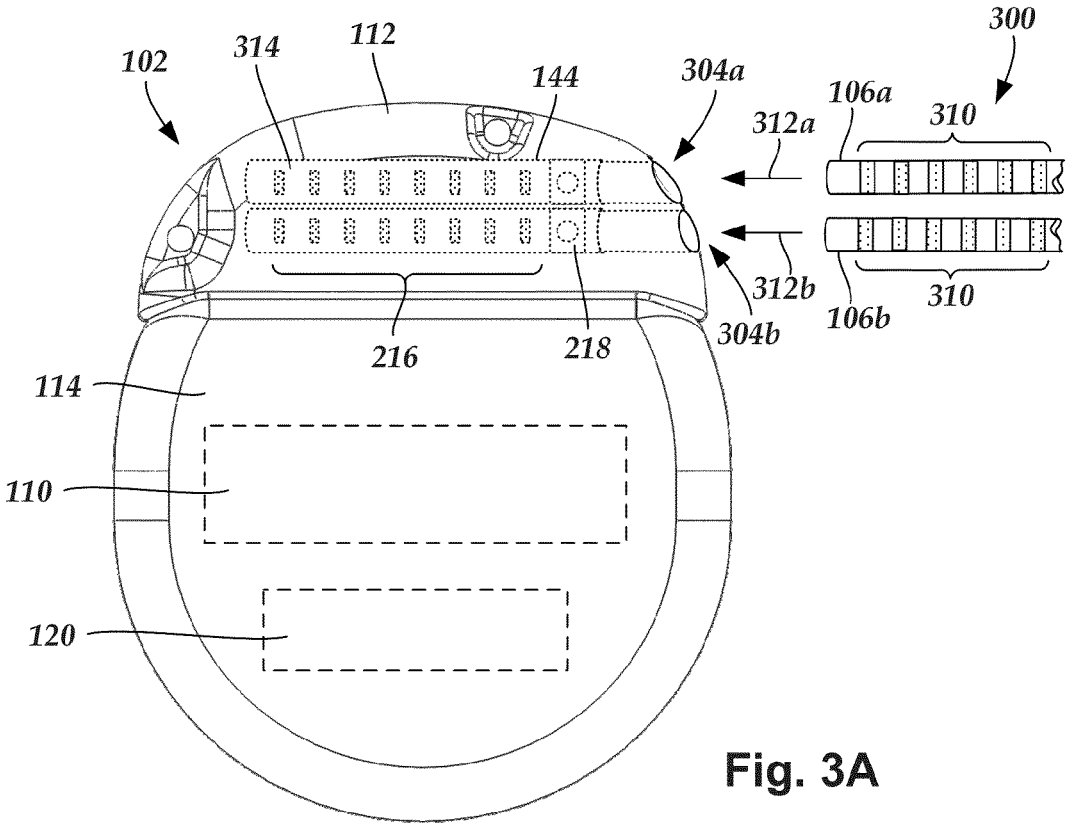
102
314
112
144
304a
300
106a
310
312a
312b
106b
310
304b
216
218
114
110
120

Fig. 3A

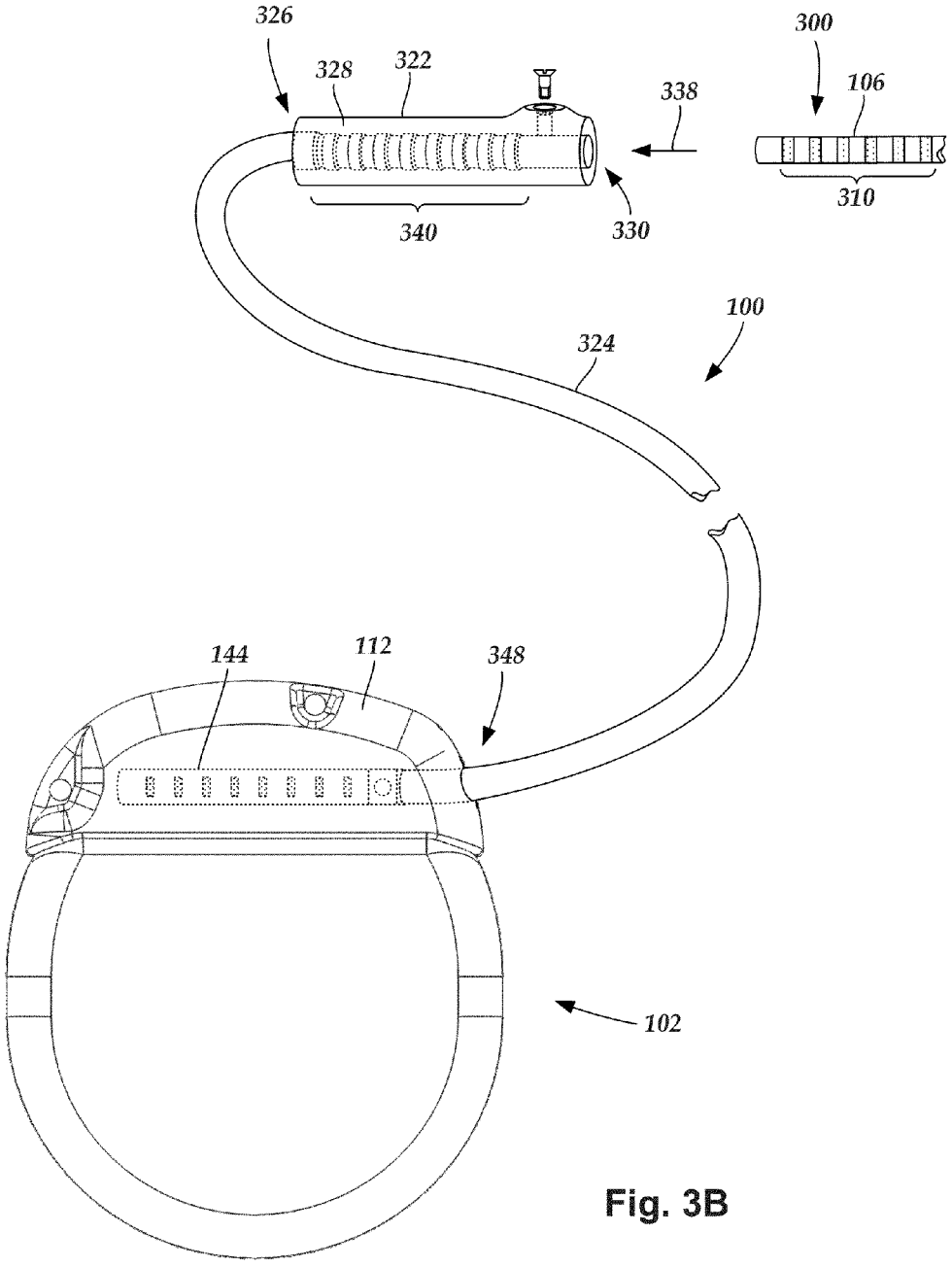

Fig. 3B

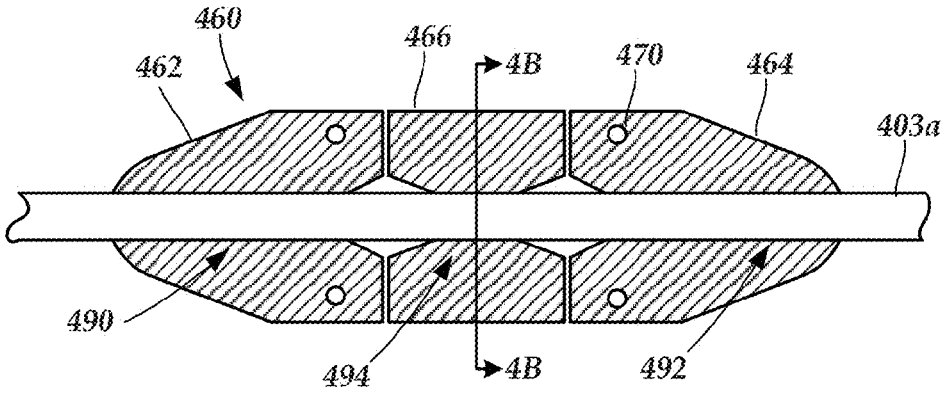

Fig. 4A

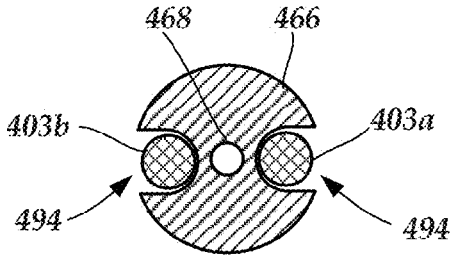

Fig. 4B

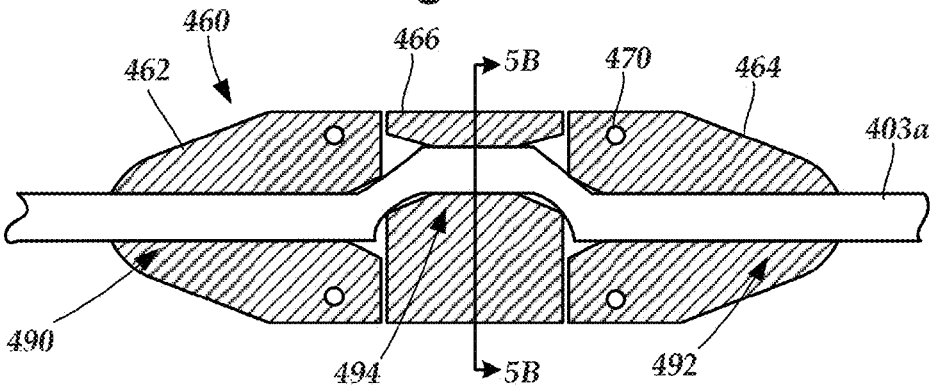

Fig. 5A

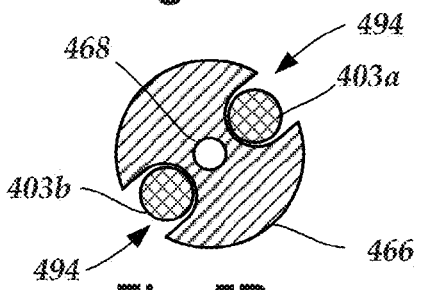

Fig. 5B

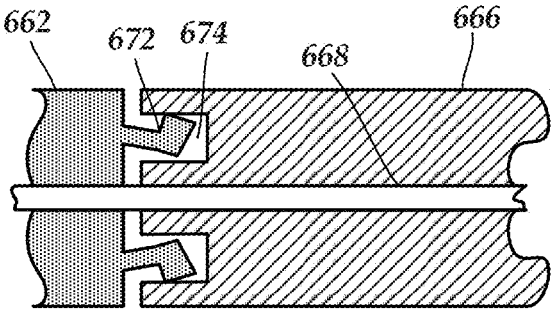

Fig. 6A

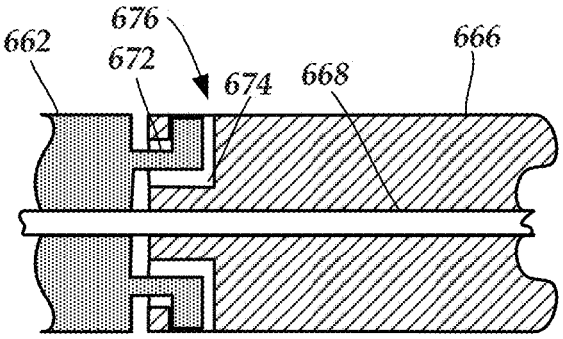

Fig. 6B

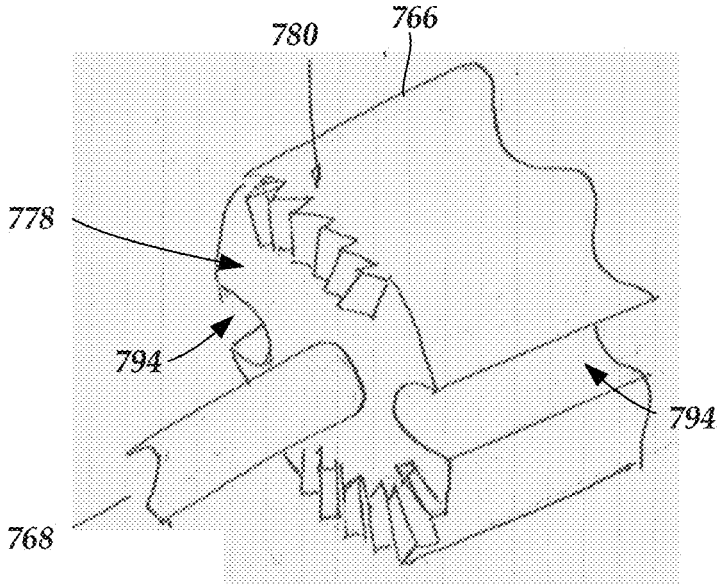

Fig. 7

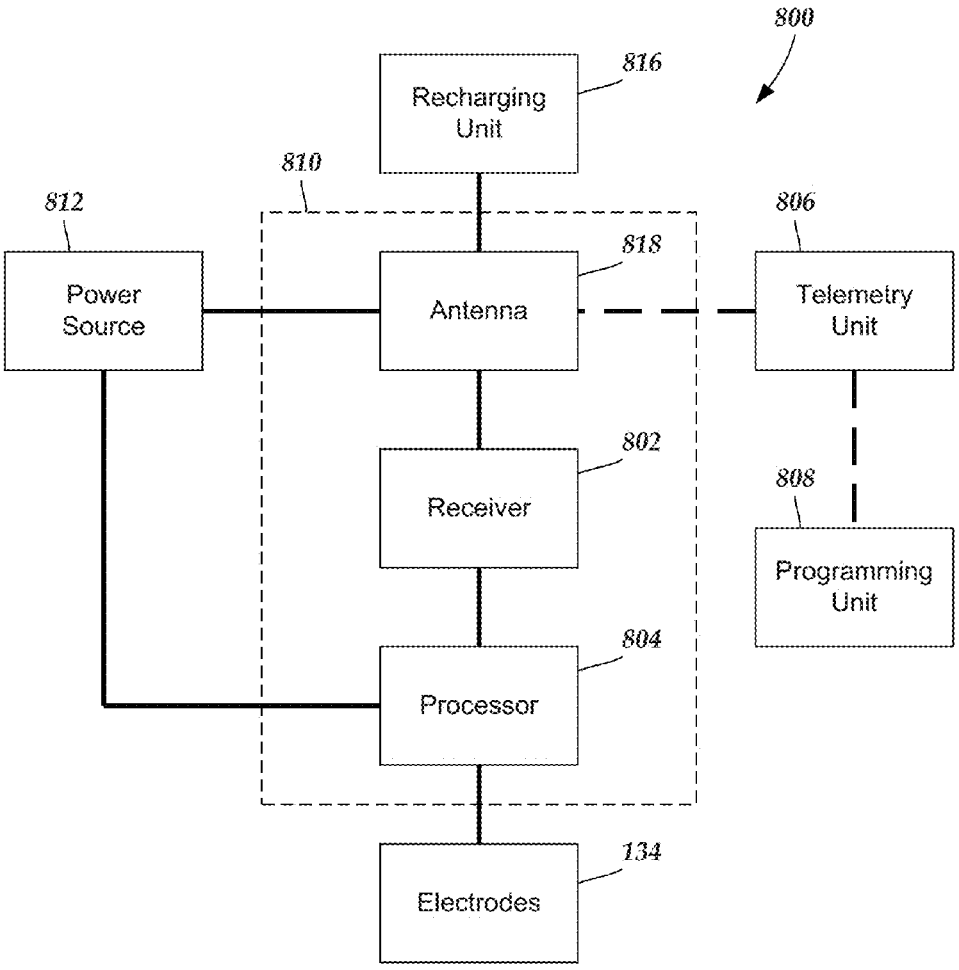
800
816
Recharging Unit
810
812
806
818
Power Source
Antenna
Telemetry Unit
802
808
Receiver
Programming Unit
804
Processor
134
Electrodes

Fig. 8

SIDE LOADING LEAD ANCHOR AND METHODS OF MAKING AND USING THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. §119 (e) of U.S. Provisional Patent Application Ser. No. 61/946,162, filed Feb. 28, 2014, which is incorporated herein by reference.

FIELD

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to a side loading anchor for receiving one or more leads, as well as methods of making and using the anchor with leads and electrical stimulation systems.

BACKGROUND

Implantable electrical stimulation systems have proven therapeutic in a variety of diseases and disorders. For example, spinal cord stimulation systems have been used as a therapeutic modality for the treatment of chronic pain syndromes. Peripheral nerve stimulation has been used to treat chronic pain syndrome and incontinence, with a number of other applications under investigation. Functional electrical stimulation systems have been applied to restore some functionality to paralyzed extremities in spinal cord injury patients.

Stimulators have been developed to provide therapy for a variety of treatments. A stimulator can include a control module (with a pulse generator), one or more leads, and an array of stimulator electrodes on each lead. The stimulator electrodes are in contact with or near the nerves, muscles, or other tissue to be stimulated. The pulse generator in the control module generates electrical pulses that are delivered by the electrodes to body tissue.

Often leads are anchored at one or more places within the body to prevent or reduce the movement of the lead or stimulator electrodes after implantation. Such undesired movement of the leads may lead to: (1) damage to surrounding tissue; (2) movement of the stimulator electrodes out of their desired positions in such a way as to reduce effectiveness of treatment; or (3) interference or interruption in the connections between the stimulator electrodes and the control module.

BRIEF SUMMARY

In one embodiment, an implantable lead anchor includes a first anchor housing including at least one first lead receiving channel and a second anchor housing including at least one second lead receiving channel. Additionally, the lead anchor includes an armature coupled to the first anchor housing and the second anchor housing and holding the first and second anchor housings in a spaced-apart arrangement. Moreover, the lead anchor includes a spindle configured and arranged to be rotatably disposed on the armature and between the first and second anchor housings. The spindle further includes at least one third lead receiving channel configured and arranged to receive and hold a portion of a lead within the at least one third lead receiving channel. In addition, a locking arrangement is formed on the spindle and at least one of the first anchor housing or second anchor housing. The locking arrangement is configured and arranged to maintain the spindle in a rotated position relative to the first and second anchor housing when the locking arrangement is activated.

In another embodiment, a kit includes the implantable lead anchor described above and at least one electrical stimulation lead. The implantable lead anchor is configured and arranged to receive a portion of one of the at least one electrical stimulation lead in the lead channel.

In yet another embodiment, a method of implanting an electrical stimulation lead includes side loading a portion of a first electrical stimulation lead into a one of the at least one third lead receiving channel of the implantable lead anchor described above. Additionally, the method includes rotating the spindle to lock the first electrical stimulation lead in the implantable lead anchor.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the present invention are described with reference to the following drawings. In the drawings, like reference numerals refer to like parts throughout the various figures unless otherwise specified.

For a better understanding of the present invention, reference will be made to the following Detailed Description, which is to be read in association with the accompanying drawings, wherein:

FIG. **1** is a schematic view of one embodiment of an electrical stimulation system that includes a paddle lead electrically coupled to a control module, according to the invention;

FIG. **2** is a schematic view of one embodiment of an electrical stimulation system that includes a percutaneous lead electrically coupled to a control module, according to the invention;

FIG. **3**A is a schematic view of one embodiment of the control module of FIG. **1** configured and arranged to electrically couple to an elongated device, according to the invention;

FIG. **3**B is a schematic view of one embodiment of a lead extension configured and arranged to electrically couple the elongated device of FIG. **2** to the control module of FIG. **1**, according to the invention;

FIG. **4**A is a schematic side view of a side loading lead anchor in a loading position, according to the invention;

FIG. **4**B is a schematic cross-sectional view of the side loading lead anchor of FIG. **4**A taken along line **4**B-**4**B, according to the invention;

FIG. **5**A is a schematic side view of a side loading lead anchor in a locked position, according to the invention;

FIG. **5**B is a schematic cross-sectional view of the side loading lead anchor of FIG. **5**A taken along line **5**B-**5**B, according to the invention;

FIG. **6**A is a schematic cross-sectional view of a locking arrangement with an annular recess and locking arms in an unlocked position, according to the invention;

FIG. **6**B is a schematic cross-sectional view of the locking arrangement of FIG. **6**A with the locking arms in the locked position, according to the invention;

FIG. **7** is a schematic perspective view of a spindle of a lead anchor with a ratcheting surface, according to the invention; and

FIG. **8** is a schematic overview of one embodiment of components of a stimulation system, including an electronic subassembly disposed within a control module, according to the invention.

DETAILED DESCRIPTION

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and

using the systems. The present invention is also directed a side loading anchor for receiving one or more leads, as well as methods of making and using the anchor with leads and electrical stimulation systems.

Suitable implantable electrical stimulation systems include, but are not limited to, a least one lead with one or more electrodes disposed along a distal end of the lead and one or more terminals disposed along the one or more proximal ends of the lead. Leads include, for example, percutaneous leads, paddle leads, and cuff leads. Examples of electrical stimulation systems with leads are found in, for example, U.S. Pat. Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,949,395; 7,244,150; 7,672,734; 7,761,165; 7,974,706; 8,175,710; 8,224,450; and 8,364,278; and U.S. Patent Application Publication No. 2007/0150036, all of which are incorporated by reference.

FIG. **1** illustrates schematically one embodiment of an electrical stimulation system **100**. The electrical stimulation system includes a control module (e.g., a stimulator or pulse generator) **102** and a lead **103** coupleable to the control module **102**. The lead **103** includes a paddle body **104** and one or more lead bodies **106**. In FIG. **1**, the lead **103** is shown having two lead bodies **106**. It will be understood that the lead **103** can include any suitable number of lead bodies including, for example, one, two, three, four, five, six, seven, eight, or more lead bodies **106**. An array **133** of electrodes, such as electrode **134**, is disposed on the paddle body **104**, and an array of terminals (e.g., **310** in FIGS. **3**A-**3**B) is disposed along each of the one or more lead bodies **106**.

It will be understood that the electrical stimulation system can include more, fewer, or different components and can have a variety of different configurations including those configurations disclosed in the electrical stimulation system references cited herein. For example, instead of a paddle body, the electrodes can be disposed in an array at or near the distal end of a lead body forming a percutaneous lead.

FIG. **2** illustrates schematically another embodiment of the electrical stimulation system **100**, where the lead **103** is a percutaneous lead. In FIG. **2**, the electrodes **134** are shown disposed along the one or more lead bodies **106**. In at least some embodiments, the lead **103** is isodiametric along a longitudinal length of the lead body **106**.

The lead **103** can be coupled to the control module **102** in any suitable manner. In FIG. **1**, the lead **103** is shown coupling directly to the control module **102**. In at least some other embodiments, the lead **103** couples to the control module **102** via one or more intermediate devices (**324** in FIG. **3**B). For example, in at least some embodiments one or more lead extensions **324** (see e.g., FIG. **3**B) can be disposed between the lead **103** and the control module **102** to extend the distance between the lead **103** and the control module **102**. Other intermediate devices may be used in addition to, or in lieu of, one or more lead extensions including, for example, a splitter, an adaptor, or the like or combinations thereof. It will be understood that, in the case where the electrical stimulation system **100** includes multiple elongated devices disposed between the lead **103** and the control module **102**, the intermediate devices may be configured into any suitable arrangement.

In FIG. **2**, the electrical stimulation system **100** is shown having a splitter **207** configured and arranged for facilitating coupling of the lead **103** to the control module **102**. The splitter **107** includes a splitter connector **108** configured to couple to a proximal end of the lead **103**, and one or more splitter tails **109***a* and **109***b* configured and arranged to couple to the control module **102** (or another splitter, a lead extension, an adaptor, or the like).

With reference to FIGS. **1** and **2**, the control module **102** typically includes a connector housing **112** and a sealed electronics housing **114**. An electronic subassembly **110** and an optional power source **120** are disposed in the electronics housing **114**. A control module connector **144** is disposed in the connector housing **112**. The control module connector **144** is configured and arranged to make an electrical connection between the lead **103** and the electronic subassembly **110** of the control module **102**.

The electrical stimulation system or components of the electrical stimulation system, including the paddle body **104**, the one or more of the lead bodies **106**, and the control module **102**, are typically implanted into the body of a patient. The electrical stimulation system can be used for a variety of applications including, but not limited to deep brain stimulation, neural stimulation, spinal cord stimulation, muscle stimulation, and the like.

The electrodes **134** can be formed using any conductive, biocompatible material. Examples of suitable materials include metals, alloys, conductive polymers, conductive carbon, and the like, as well as combinations thereof. In at least some embodiments, one or more of the electrodes **134** are formed from one or more of: platinum, platinum iridium, palladium, palladium rhodium, or titanium.

Any suitable number of electrodes **134** can be disposed on the lead including, for example, four, five, six, seven, eight, nine, ten, eleven, twelve, fourteen, sixteen, twenty-four, thirty-two, or more electrodes **134**. In the case of paddle leads, the electrodes **134** can be disposed on the paddle body **104** in any suitable arrangement. In FIG. **1**, the electrodes **134** are arranged into two columns, where each column has eight electrodes **134**.

The electrodes of the paddle body **104** (or one or more lead bodies **106**) are typically disposed in, or separated by, a non-conductive, biocompatible material such as, for example, silicone, polyurethane, polyetheretherketone ("PEEK"), epoxy, and the like or combinations thereof. The one or more lead bodies **106** and, if applicable, the paddle body **104** may be formed in the desired shape by any process including, for example, molding (including injection molding), casting, and the like. The non-conductive material typically extends from the distal ends of the one or more lead bodies **106** to the proximal end of each of the one or more lead bodies **106**.

In the case of paddle leads, the non-conductive material typically extends from the paddle body **104** to the proximal end of each of the one or more lead bodies **106**. Additionally, the non-conductive, biocompatible material of the paddle body **104** and the one or more lead bodies **106** may be the same or different. Moreover, the paddle body **104** and the one or more lead bodies **106** may be a unitary structure or can be formed as two separate structures that are permanently or detachably coupled.

Terminals (e.g., **310** in FIGS. **3**A-**3**B) are typically disposed along the proximal end of the one or more lead bodies **106** of the electrical stimulation system **100** (as well as any splitters, lead extensions, adaptors, or the like) for electrical connection to corresponding connector contacts (e.g., **314** in FIG. **3**A). The connector contacts are disposed in connectors (e.g., **144** in FIGS. **1**-**3**B; and **322** FIG. **3**B) which, in turn, are disposed on, for example, the control module **102** (or a lead extension, a splitter, an adaptor, or the like). Electrically conductive wires, cables, or the like (not shown) extend from the terminals to the electrodes **134**. Typically, one or more electrodes **134** are electrically coupled to each terminal. In at least some embodiments, each terminal is only connected to one electrode **134**.

The electrically conductive wires ("conductors") may be embedded in the non-conductive material of the lead body **106** or can be disposed in one or more lumens (not shown) extending along the lead body **106**. In some embodiments, there is an individual lumen for each conductor. In other embodiments, two or more conductors extend through a lumen. There may also be one or more lumens (not shown) that open at, or near, the proximal end of the one or more lead bodies **106**, for example, for inserting a stylet to facilitate placement of the one or more lead bodies **106** within a body of a patient. Additionally, there may be one or more lumens (not shown) that open at, or near, the distal end of the one or more lead bodies **106**, for example, for infusion of drugs or medication into the site of implantation of the one or more lead bodies **106**. In at least one embodiment, the one or more lumens are flushed continually, or on a regular basis, with saline, epidural fluid, or the like. In at least some embodiments, the one or more lumens are permanently or removably sealable at the distal end.

FIG. **3**A is a schematic side view of one embodiment of a proximal end of one or more elongated devices **300** configured and arranged for coupling to one embodiment of the control module connector **144**. The one or more elongated devices may include, for example, one or more of the lead bodies **106** of FIG. **1**, one or more intermediate devices (e.g., a splitter, the lead extension **324** of FIG. **3**B, an adaptor, or the like or combinations thereof), or a combination thereof.

The control module connector **144** defines at least one port into which a proximal end of the elongated device **300** can be inserted, as shown by directional arrows **312***a* and **312***b*. In FIG. **3**A (and in other figures), the connector housing **112** is shown having two ports **304***a* and **304***b*. The connector housing **112** can define any suitable number of ports including, for example, one, two, three, four, five, six, seven, eight, or more ports.

The control module connector **144** also includes a plurality of connector contacts, such as connector contact **314**, disposed within each port **304***a* and **304***b*. When the elongated device **300** is inserted into the ports **304***a* and **304***b*, the connector contacts **314** can be aligned with a plurality of terminals **310** disposed along the proximal end(s) of the elongated device(s) **300** to electrically couple the control module **102** to the electrodes (**134** of FIG. **1**) disposed on the paddle body **104** of the lead **103**. Examples of connectors in control modules are found in, for example, U.S. Pat. Nos. 7,244,150 and 8,224,450, which are incorporated by reference.

FIG. **3**B is a schematic side view of another embodiment of the electrical stimulation system **100**. The electrical stimulation system **100** includes a lead extension **324** that is configured and arranged to couple one or more elongated devices **300** (e.g., one of the lead bodies **106** of FIGS. **1** and **2**, the splitter **207** of FIG. **2**, an adaptor, another lead extension, or the like or combinations thereof) to the control module **102**. In FIG. **3**B, the lead extension **324** is shown coupled to a single port **304** defined in the control module connector **144**. Additionally, the lead extension **324** is shown configured and arranged to couple to a single elongated device **300**. In alternate embodiments, the lead extension **324** is configured and arranged to couple to multiple ports **304** defined in the control module connector **144**, or to receive multiple elongated devices **300**, or both.

A lead extension connector **322** is disposed on the lead extension **324**. In FIG. **3**B, the lead extension connector **322** is shown disposed at a distal end **326** of the lead extension **324**. The lead extension connector **322** includes a connector housing **328**. The connector housing **328** defines at least one port **330** into which terminals **310** of the elongated device **300** can be inserted, as shown by directional arrow **338**. The connector housing **328** also includes a plurality of connector contacts, such as connector contacts **340**. When the elongated device **300** is inserted into the port **330**, the connector contacts **340** disposed in the connector housing **328** can be aligned with the terminals **310** of the elongated device **300** to electrically couple the lead extension **324** to the electrodes (**134** of FIGS. **1** and **2**) disposed along the lead (**103** in FIGS. **1** and **2**).

In at least some embodiments, the proximal end of the lead extension **324** is similarly configured and arranged as a proximal end of the lead **103** (or other elongated device **300**). The lead extension **324** may include a plurality of electrically conductive wires (not shown) that electrically couple the connector contacts **340** to a proximal end **348** of the lead extension **324** that is opposite to the distal end **326**. In at least some embodiments, the conductive wires disposed in the lead extension **324** can be electrically coupled to a plurality of terminals (not shown) disposed along the proximal end **348** of the lead extension **324**. In at least some embodiments, the proximal end **348** of the lead extension **324** is configured and arranged for insertion into a connector disposed in another lead extension (or another intermediate device). In other embodiments (and as shown in FIG. **3**B), the proximal end **348** of the lead extension **324** is configured and arranged for insertion into the control module connector **144**.

After implantation, there is a risk that the body of the lead (e.g., **103** in FIG. **1**) or the lead extension (e.g., **324** in FIG. **3**B) may move inadvertently from a desired location within a patient's body. To prevent or reduce the inadvertent movement of the lead **103** or the lead extension **324** (also referred to as "lead migration"), one or more lead anchors may hold the lead **103** or the lead extension **324** in place within the patient tissue. FIGS. **4**A and **4**B illustrate a side loading lead anchor **460** to hold at least one lead within a patient's body.

FIG. **4**A is a schematic side view of the side loading lead anchor **460** in a loading position. FIG. **4**B is a schematic cross-sectional view of the side loading lead anchor **460** of FIG. **4**A taken along line **4**B-**4**B. In some embodiments, as shown, the lead anchor **460** has a substantially cylindrical shape. Other suitable shapes of the lead anchor **460** include spheroidal, polygonal, or any other shape, preferably with rounded edges or vertices. The lead anchor **460** has suitable dimensions to be implanted within a patient's body. In some embodiments, the length of the lead anchor **460** ranges from 1 cm to 5 cm. In other embodiments, the length of the lead anchor **460** ranges from 2 cm to 3 cm. In addition, in some embodiments, the largest radial diameter of the lead anchor **460** ranges from 4 mm to 30 mm. In other embodiments, the largest radial diameter of the lead anchor **460** ranges from 5 mm to 15 mm.

The lead anchor **460** includes a first anchor housing **462**, a second anchor housing **464**, a spindle **466**, and an armature **468** (shown in FIG. **4**B). In some embodiments, the first and the second anchor housings **462** and **464** have a substantially cylindrical shape. Other suitable shapes for the first and the second anchor housings **462** and **464** includes conical, frustum, hemispheroidal, polygonal, and any other shape, preferably with rounded or smooth atraumatic edges and vertices.

In at least some embodiments, the armature **468** is coupled to the first anchor housing **462** and the second anchor housing **464**. The armature **468** can be a cylindrical shaft or tube. The armature **468** maintains the first and second anchor housings **462** and **464** in a spaced-apart arrangement. For example, in some embodiments, the armature **468** is fixedly disposed in a central lumen (not shown) that extends through a central axis of the first and second housing **462** and **464**. In other embodiments, the armature **468** is attached to the laterally opposing

surfaces of the first and second housings **462** and **464** by any suitable biocompatible attachment means such as adhesives, screws, rivets, or the like. In other embodiments, the armature **468** is molded as a part of one or both of the first and second housings **462** and **464**.

As shown in FIG. **4**A, there is a gap between the first and second anchor housings **462** and **464**, where the spindle **466** is located. The spindle **466** is rotatably disposed on the armature **468** between the first anchor housing **462** and the second anchor housing **464**.

In at least some embodiments, as shown, the spindle **466** has a substantially cylindrical shape. Any other suitable shape, preferably having rounded or smooth atraumatic edges and vertices, can be used to make the spindle **466**. For example, in some embodiments, the spindle **466** has a hexagonal shape with smooth edges and vertices.

In some embodiments, a method of making the lead anchor **460** includes fixedly attaching the first anchor housing **462** or the second anchor housing **464** to the armature **468**. Then, the spindle **466** is disposed on the armature **468** followed by fixed attachment of the other anchor housing to the armature **468**.

In some embodiments, to prevent or reduce any impediment in rotation of the spindle **466**, the first and the second anchor housings **462** and **464** has a generally flat surface facing the spindle **466**. Similarly, the spindle **466** has a generally flat surface facing each of the first and the second anchor housings **462** and **464**.

The lead anchor **460** is typically sutured to the patient's tissue. To facilitate suturing of the lead anchor **460**, one or both of the first and second anchor housing **462** and **464** has at least one suture hole **470**. In some embodiments, the first and the second anchor housings **462** and **464** have two or more suture holes **470** to facilitate suturing of the lead anchor **460**.

In at least some embodiments, the lead anchor (such as lead anchor **460** in FIG. **4**A) is made of a MRI-compatible material. For examples, the first anchor housing **462**, second anchor housing **464**, the spindle **466** and armature **468** can be made of a rigid biocompatible polymeric material, such as, polytetrafluoroethylene (PTFE or TEFLON™), polyethylene terephthalate (PET or DACRON™), polyvinyl chloride (PVC), polycarbonate, polyether ether ketone (PEEK), or the like or combinations thereof.

In some embodiments, the central lumen (not shown) of the spindle **466** and the surface of the armature **468** in contact with the central lumen of the spindle **466** are coated with a biocompatible material that reduces friction. Some examples of such friction-reducing materials include, but are not limited to, polytetrafluoroethylene (PTFE), tetrafluoroethylene (TFE), polyethylene terephthalate (PET or DACRON™) or the like or combinations thereof.

The lead anchor **460** secures leads or lead extensions by engaging them in one or more side loading channels. As shown in FIGS. **4**A and **4**B, in at least some embodiments, the first anchor housing **462** includes a first pair of lead receiving channels **490** for securing two leads on two laterally opposing sides along the circumference of the lead anchor **460**. Similarly, the second anchor housing **464** includes a second pair of lead receiving channels **492**, and the spindle **466** has a third pair of lead receiving channels **494**. In a loading position, the channels **490**, **492**, and **494** are coaxially arranged to form two substantially straight channels in which the two leads **403***a* and **403***b* can be loaded and secured to the lead anchor **460**.

In some embodiments, the channels **490**, **492**, and **494** have constricted openings (not shown) at the laterally opposing sides of the lead anchor **460**, such that an operator needs to apply a threshold force to push or pull leads **403***a* and **403***b* in and out of the channels **490**, **492**, and **494** through the constricted openings. The threshold force prevents or reduces the probability of the leads **403***a* and **403***b* inadvertently disengaging from the channels **490**, **492**, and **494**.

In at least some embodiments, after loading the leads **403***a* and **403***b* in the channels **490**, **492**, and **494**, the spindle **466** is rotated clockwise or counter-clockwise, to misalign the channels **494** from the channels **490** and **492** and introduce a kink or tortuous path to the leads **403***a* and **403***b*. In addition, the lead anchor **460** includes a locking arrangement (shown in FIGS. **6**A-**6**B, and FIG. **7**), which is configured and arranged to lock the spindle **466** in a rotated position and maintain the kink introduced in the leads **403***a* and **403***b* (shown in FIGS. **5**A and **5**B). Moreover, in some embodiments, the spindle **466** includes markings to indicate the extent of rotation and the locking position.

FIGS. **5**A and **5**B illustrate the spindle **466** in the rotated and locked position. FIG. **5**A is a schematic side view of the side loading lead anchor **460** in the locked position, and FIG. **5**B is a schematic cross-sectional view of the side loading lead anchor **460** of FIG. **5**A taken along line **5**B-**5**B. As shown, the spindle **466** is maintained in the rotated position relative to the first and second anchor housing **462** and **464**. In at least some embodiments, rotation of the spindle **466** creates a tortuous path for the leads **403***a*, **403***b* through the lead anchor **460**. The rotation of the spindle **466** can introduce a kink in the leads **403***a* and **403***b* which increases friction between the leads **403***a* and **403***b* and the lead receiving channels **490**, **492**, and **494**. The increased friction prevents or reduces disengagement or sliding of the leads **403***a* and **403***b* within the channels **490**, **492**, and **494**.

In some instances, rotation of the spindle **466** might cause longitudinal displacement of the distal or proximal portion of the leads **403***a* and **403***b*. Longitudinal displacement of the distal portion of the leads **403***a* and **403***b* could result in inadvertent displacement or dislodgement of the electrodes **134** from the patient's tissue. To prevent or reduce longitudinal displacement of the leads **403***a* and **403***b* in the distal direction, in some embodiments, the first anchor housing **462** or the second anchor housing **464** is positioned distally, facing towards the distal end of the leads **403***a* and **403***b*, with the channel of that particular anchor housing having an internal diameter selected to grip the portions of the leads **403***a* and **403***b* disposed in the channel. The smaller diameter of the channel allows the channel to hold the leads **403***a* and **403***b* more firmly. The firmly gripped distal end of the leads **403***a* and **403***b* in channels **490** restricts the longitudinal displacement of the leads **403***a* and **403***b* arising from rotation of the spindle **466**.

Any suitable locking arrangement can be used in the lead anchor **460**. FIGS. **6**A and **6**B depict a locking arrangement that maintains the spindle **466** in a rotated position relative to the first and second anchor housings **462** and **464**. FIG. **6**A is a schematic cross-sectional view of a locking arrangement with an annular recess **674** and locking arm **672** in an unlocked position. As shown, in some embodiments, a first anchor housing **662** has one or more locking arms **672** extending or protruding out of a surface abutting a spindle **666**. The locking arm(s) **672** extend into an annular recess **674** on the corresponding surface of the spindle **666**. In other embodiments, the second anchor housing **664** or both first and second anchor housings **662** and **664** can have one or more locking arms **672**. In yet other embodiments, the spindle **666** can have one or more locking arms **672** and the annular recess **674** can be disposed on the first or second anchor housings **662** or **664** (or both the first and second anchor housings).

In some embodiments, the locking arms **672** have a slightly longer length than the depth of the groove of the annular recess **674**, thereby the locking arms **672** are slightly tensed in the annular recess **674**. The locking arms **672** travel into the annular recess **674** upon rotation of the spindle **666** over the armature **668**. FIG. **6**B is a schematic cross-sectional view of the locking arrangement of FIG. **6**A with the locking arms **672** in the locked position. The annular recess **674** includes at least one radial opening **676** at an angular displacement from the position of the lead receiving channels **494** (FIG. **4**B). Radial opening **676** engages the locking arm **672** as the locking arm **672** travels in the annular recess **674** so that a portion of the locking arm extends into the radial opening. Upon engaging with the radial opening **676**, the locking arm **672** restricts the rotational movement of the spindle **666**, thereby, locking the spindle **666** in a rotated position. In some embodiments, the above discussed locking arrangement can be unlocked by pushing the locking arm **672** out of the radial opening **676** and into the annular recess **674** and then rotating the spindle **666**.

FIG. **7** illustrates another locking arrangement including ratcheting surfaces formed on the spindle **766** and one or both of the first and second anchor housings **462** and **464**. FIG. **7** is a schematic perspective view of a spindle **766** of a lead anchor with a ratcheting surface **778**. Although not shown here, either or both of the opposing surfaces of the first and second anchor housings **462** and **464** (shown in FIG. **4**A) contain opposing ratcheting surfaces (not shown). The ratcheting surface **778** and the ratcheting surface on the corresponding first or the second anchor housings **462** and **464** include a number of beveled teeth **780**. In at least some embodiments, the beveled teeth **780** are sloped in one direction (clockwise or anti-clockwise) and are perpendicular in the other direction (clockwise or anti-clockwise). For example, in some embodiments, the beveled teeth **780** are sloped in a clockwise direction and are perpendicular in anti-clockwise direction. The spindle **766** can be rotated in the clockwise direction such that the opposing ratcheting surfaces mate together and move over the sloping surface of the teeth **780**. Rotation in the anti-clockwise direction is stopped by the perpendicular surface of the teeth **780**. Additionally, an operator needs to apply sufficient force to overcome friction to rotate the spindle **766** in clockwise direction. After rotation of the spindle **766** by the operator in clockwise direction, the frictional force prevents or reduces free rotation of the spindle **766** in the clockwise direction and locks the spindle **766** in the rotated position.

In at least some embodiments, the armature **768** is longitudinally flexible or elastic. The flexible armature **778** provides an inward longitudinal tensile force within the lead anchor **760**. The tensile force increases friction between the ratcheting surfaces of the spindle **766** and the corresponding ratcheting surfaces of the first or second anchor housings **462** and **464**. The flexible armature **778** allows the locking mechanism to be released from a locked state, described above, by grasping and pulling the first and second anchor housing **462**,**464** away from each other to decouple the ratcheting surfaces and allow rotation of the spindle **766** back to its original position. The armature **778** can be made of a flexible or elastic polymeric material such as silicone, rubber, or the like.

Referring to FIGS. **4**A-**7**, any suitable manufacturing method capable of making the lead anchor **460** with the locking features, such as locking arms **672**, annular recess **674**, or ratcheting surface **778** with teeth **780** illustrated in FIGS. **6**A, **6**B, and **7** can be used to manufacture the lead anchor **460**. Some examples of manufacturing the first and second anchor housings **462** and **464**, spindle **466**, and armature **468** may include, but are not limited to, molding, extrusion, selective laser sintering (SLS), selective heat sintering (SHS), or fused deposition modeling (FDM). Additionally, medical adhesive or a polymer reflow process can be utilized for attaching the armature **468** to the first and second anchor housings **462** and **464**.

One embodiment of an electrical stimulation system is a kit including the implantable lead anchor **460** and one or more leads **103** (paddle lead shown in FIG. **1** or the percutaneous lead shown in FIG. **2**). Optionally, the kit includes a lead extension **324** or a control module or both. In some embodiments, the lead **103** couples to the control module to complete the circuit of the electrical stimulation system. In some other embodiments, the lead **103** couples to the lead extension **324**, and the lead extension **324** couples to the control module to complete the circuit of the electrical stimulation system. The implantable lead anchor **460** receives a portion of the lead **103** or lead extension **324** in the lead channels **490**, **492**, and **494** and anchors the lead **103** or lead extension **324** to patient tissue.

Referring to FIGS. **4**A and **4**B, according to some embodiments, a method of implanting an electrical stimulation system includes the following steps. An operator side loads portions of one or more electrical stimulation leads (for example, leads **403***a* and **403***b*) into the lead receiving channels **490**, **492**, and **494** of the implantable lead anchor **460**. The operator then rotates the spindle **466** to lock the electrical stimulation leads in the implantable lead anchor **460**. A locking arrangement locks the stimulation leads within the lead anchor **460**. One example of a suitable locking arrangement is illustrated with FIGS. **6**A and **6** where, upon rotation of the spindle **666**, the radial openings **676** in the annular recess **674** receive the locking arms **672** locking the spindle **666**. Another example of a suitable locking arrangement is illustrated with FIG. **7** where, after rotation of the spindle **766** by the operator, the beveled teeth **780** on opposing ratcheting surfaces disallows rotation of the spindle **766** in one direction and the frictional force prevents or restricts rotation of the spindle **766** in the other direction. Once, the operator has rotated the spindle **766**, the spindle **766** is locked in the rotated position. The operator also sutures the lead anchor **460** to patient tissue.

FIG. **8** is a schematic overview of one embodiment of components of an electrical stimulation system **800** including an electronic subassembly **810** disposed within a control module. It will be understood that the electrical stimulation system can include more, fewer, or different components and can have a variety of different configurations including those configurations disclosed in the stimulator references cited herein.

Some of the components (for example, a power source **812**, an antenna **818**, a receiver **802**, and a processor **804**) of the electrical stimulation system can be positioned on one or more circuit boards or similar carriers within a sealed housing of an implantable pulse generator, if desired. Any power source **812** can be used including, for example, a battery such as a primary battery or a rechargeable battery. Examples of other power sources include super capacitors, nuclear or atomic batteries, mechanical resonators, infrared collectors, thermally-powered energy sources, flexural powered energy sources, bioenergy power sources, fuel cells, bioelectric cells, osmotic pressure pumps, and the like including the power sources described in U.S. Pat. No. 7,437,193, incorporated herein by reference.

As another alternative, power can be supplied by an external power source through inductive coupling via the optional antenna **818** or a secondary antenna. The external power

source can be in a device that is mounted on the skin of the user or in a unit that is provided near the user on a permanent or periodic basis.

If the power source **812** is a rechargeable battery, the battery may be recharged using the optional antenna **818**, if desired. Power can be provided to the battery for recharging by inductively coupling the battery through the antenna to a recharging unit **816** external to the user. Examples of such arrangements can be found in the references identified above.

In one embodiment, electrical current is emitted by the electrodes **134** on the paddle or lead body to stimulate nerve fibers, muscle fibers, or other body tissues near the electrical stimulation system. The processor **804** is generally included to control the timing and electrical characteristics of the electrical stimulation system. For example, the processor **804** can, if desired, control one or more of the timing, frequency, strength, duration, and waveform of the pulses. In addition, the processor **804** can select which electrodes can be used to provide stimulation, if desired. In some embodiments, the processor **804** selects which electrode(s) are cathodes and which electrode(s) are anodes. In some embodiments, the processor **804** is used to identify which electrodes provide the most useful stimulation of the desired tissue.

Any processor can be used and can be as simple as an electronic device that, for example, produces pulses at a regular interval or the processor can be capable of receiving and interpreting instructions from an external programming unit **808** that, for example, allows modification of pulse characteristics. In the illustrated embodiment, the processor **804** is coupled to a receiver **802** that, in turn, is coupled to the optional antenna **818**. This allows the processor **804** to receive instructions from an external source to, for example, direct the pulse characteristics and the selection of electrodes, if desired.

In one embodiment, the antenna **818** is capable of receiving signals (e.g., RF signals) from an external telemetry unit **806** that is programmed by the programming unit **808**. The programming unit **808** can be external to, or part of, the telemetry unit **806**. The telemetry unit **806** can be a device that is worn on the skin of the user or can be carried by the user and can have a form similar to a pager, cellular phone, or remote control, if desired. As another alternative, the telemetry unit **806** may not be worn or carried by the user but may only be available at a home station or at a clinician's office. The programming unit **808** can be any unit that can provide information to the telemetry unit **806** for transmission to the electrical stimulation system **800**. The programming unit **808** can be part of the telemetry unit **806** or can provide signals or information to the telemetry unit **806** via a wireless or wired connection. One example of a suitable programming unit is a computer operated by the user or clinician to send signals to the telemetry unit **806**.

The signals sent to the processor **804** via the antenna **818** and the receiver **802** can be used to modify or otherwise direct the operation of the electrical stimulation system. For example, the signals may be used to modify the pulses of the electrical stimulation system such as modifying one or more of pulse duration, pulse frequency, pulse waveform, and pulse strength. The signals may also direct the electrical stimulation system **800** to cease operation, to start operation, to start charging the battery, or to stop charging the battery. In other embodiments, the stimulation system does not include the antenna **818** or receiver **802** and the processor **804** operates as programmed.

Optionally, the electrical stimulation system **800** may include a transmitter (not shown) coupled to the processor **804** and the antenna **818** for transmitting signals back to the telemetry unit **806** or another unit capable of receiving the signals. For example, the electrical stimulation system **800** may transmit signals indicating whether the electrical stimulation system **800** is operating properly or not or indicating when the battery needs to be charged or the level of charge remaining in the battery. The processor **804** may also be capable of transmitting information about the pulse characteristics so that a user or clinician can determine or verify the characteristics.

The above specification, examples, and data provide a description of the manufacture and use of the composition of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention also resides in the claims hereinafter appended.

The invention claimed is:

1. An implantable lead anchor, comprising:

a first anchor housing comprising at least one first lead receiving channel;

a second anchor housing comprising at least one second lead receiving channel;

an armature coupled to the first anchor housing and the second anchor housing and holding the first and second anchor housings in a spaced-apart arrangement;

a spindle configured and arranged to be rotatably disposed on the armature and between the first and second anchor housings, wherein the spindle comprises at least one third lead receiving channel configured and arranged to receive and hold a portion of a lead within the at least one third lead receiving channel; and

a locking arrangement formed on the spindle and at least one of the first anchor housing or second anchor housing, wherein the locking arrangement is configured and arranged to maintain the spindle in a rotated position relative to the first and second anchor housing when the locking arrangement is activated.

2. The implantable lead anchor of claim **1**, wherein the first anchor housing comprises two first lead receiving channels, the second anchor housing comprises two second lead receiving channels, and the spindle comprises two third lead receiving channels.

3. The implantable lead anchor of claim **1**, wherein the locking arrangement comprises at least one locking arm extending from the first or second anchor housing, a corresponding annular recess in the spindle for receiving the at least one locking arm, and at least one radial opening extending from the annular recess and configured and arranged to receive a portion of the at least one locking arm to lock the at least one locking arm.

4. The implantable lead anchor of claim **1**, wherein the locking arrangement comprises at least one locking arm extending from the spindle, a corresponding annular recess in the first or second anchor housing for receiving the at least one locking arm, and at least one radial opening extending from the annular recess and configured and arranged to receive a portion of the at least one locking arm to lock the at least one locking arm.

5. The implantable lead anchor of claim **1**, wherein the locking arrangement comprises opposing ratcheting surfaces formed on the spindle and on at least one of the first or second anchor housing.

6. The implantable lead anchor of claim **5**, wherein each of the opposing ratcheting surfaces comprises a plurality of beveled teeth arranged around at least a portion of the ratcheting surface.

7. The implantable lead anchor of claim 1, wherein the first anchor housing defines at least one suture hole through the first anchor housing.

8. The implantable lead anchor of claim 7, wherein the second anchor housing defines at least one suture hole through the second anchor housing.

9. The implantable lead anchor of claim 1, wherein the armature is longitudinally flexible so that the locking arrangement can be released from a locked state by grasping the first and second anchor housing and pulling the first and second anchor housings away from each other.

10. The implantable lead anchor of claim 1, wherein the lead anchor is formed entirely of non-metallic materials.

11. A kit, comprising:

the implantable lead anchor of claim 1; and

at least one electrical stimulation lead, wherein the implantable lead anchor is configured and arranged to receive a portion of one of the at least one electrical stimulation lead in the at least one third lead receiving channel.

12. The kit of claim 11, further comprising a control module coupleable to the at least one electrical stimulation lead.

13. The kit of claim 12, further comprising a lead extension coupleable to the lead and to the control module.

14. A method of implanting an electrical stimulation lead, the method comprising:

side loading a portion of a first electrical stimulation lead into a one of the at least one third lead receiving channel of the implantable lead anchor of claim 1; and

rotating the spindle to lock the first electrical stimulation lead in the implantable lead anchor.

15. The method of claim 14, wherein the first anchor housing comprises two first lead receiving channels, the second anchor housing comprises two second lead receiving channels, and the spindle comprises two third lead receiving channels.

16. The method of claim 15, further comprising side loading a portion of a second electrical stimulation lead into another one of the third lead receiving channels of the implantable lead anchor.

17. The method claim 15, wherein the locking arrangement comprises at least one locking arm extending from the first or second anchor housing, a corresponding annular recess in the spindle for receiving the at least one locking arm, and at least one radial opening extending from the annular recess and configured and arranged to receive a portion of the at least one locking arm to lock the at least one locking arm; and

wherein rotating the spindle comprises receiving the portion of the at least one locking arm into the at least one radial opening to lock the at least one locking arm.

18. The method claim 15, wherein the locking arrangement comprises at least one locking arm extending from the spindle, a corresponding annular recess in the first or second anchor housing for receiving the at least one locking arm, and at least one radial opening extending from the annular recess and configured and arranged to receive a portion of the at least one locking arm to lock the at least one locking arm; and

wherein rotating the spindle comprises receiving the portion of the at least one locking arm into the at least one radial opening to lock the at least one locking arm.

19. The method claim 15, wherein the locking arrangement comprises opposing ratcheting surfaces formed on the spindle and on at least one of the first or second anchor housing; and

wherein rotating the spindle comprises rotating the opposing ratcheting surfaces relative to each other to a desired locked position.

20. The method of claim 15, further comprising suturing the lead anchor to patient tissue.

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